CE IVD

REF m-101

mLabs® ImmunoMeter

User's Manual

For Health Care Professional Use Only

MICROPOINT

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1. Introduction

1.1 How to Use this Manual

This user manual contains important information regarding the proper operation and maintenance of the mLabs® ImmunoMeter.

The mLabs® ImmunoMeter User Manual consists of seven sections:

1. Introduction: An overview of mLabs® ImmunoMeter
2. Installation and Configuration: Guides through first time setup
3. Operation: Instructs how to run tests, view and delete results
4. Maintenance
5. Troubleshooting
6. Warranty
7. Contact Addresses and Phone Numbers

1.2 Introduction

1.2.1 The mLabs® ImmunoMeter Components

- One mLabs® ImmunoMeter, as shown in Fig. 1-1.

Fig. 1-1

- User Manual
- One power cable and one power adapter, as shown in Fig. 1-2.

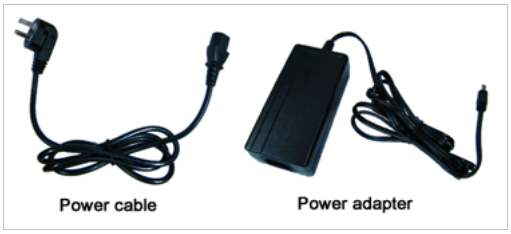


Fig. 1-2

- One roll of printer paper, as shown in Fig. 1-3.

Fig. 1-3

- One Calibration Cartridge, as shown in Fig. 1-4.

Fig. 1-4

(Calibration Cartridge barcode number may be different than shown.)

- One Touch Pen, as shown in Fig. 1-5.

Fig. 1-5

Optional Accessory (available from Micropoint): Barcode Scanner, as shown in Fig. 1-6.

Fig. 1-6

Contact your local Micropoint distributor to obtain information about the replacement of the power adapter & cable, printing paper, and Calibration Cartridge, touch pen, and barcode scanner if necessary.

1.2.2 Diagram of mLabs® ImmunoMeter

Front Panel:

(1) LCD Touch Screen
(2) Warning Light
(3) Status Light
(4) Power Light
(5) Cartridge Holder
(6) Cartridge Holder Eject Button
(7) Power On/Off Button

Rear Panel:

(8) Power Cable Connector
(9) RS232 Serial Port
(10) Ethernet Interface
(11) SD Card Slot
(12) USB Ports (x2)
(13) Thermal Printer (inside)

Fig 1-7

1.3 Specifications

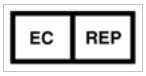
Display Screen	5.7” True Color Screen
Keyboard	Touch Screen
I/O	USB Ports ×2, Ethernet Interface ×1, RS232 Serial Port ×1, SD Card Slot ×1
Printer	Built-in 50 mm Thermal Printer
Print paper	Width: 58 mm, Outside Diameter: 50mm
OS	Windows CE
Language	English
Patient Records	1000 Test Results
Dimension	296 mm x 224 mm x 268 mm (L×W×H)
Weight	3.0 Kg
Power	Adapter Input:100V-240 V AC, 50-60 HZ ImmunoMeter Input: 12 V DC, 50 W
Environment	Indoor use only Altitude should be <2,000 m Temp: 5°C~40°C Related Humidity: ≤80% Avoid direct exposure to sunlight and strong magnetic field
Warranty Period	1 Year

1.4 Warnings, Precautions and Limitations

CAUTION: mLabs® ImmunoMeter is for in vitro diagnosis use only.

- Read the manual carefully prior to operation.
- Test results are intended only for applications specified in the product insert.
- Use the provided AC/DC power adapter and ensure that mLabs® ImmunoMeter is operated within the recommended voltage.
- Immediately unplug the AC/DC power adapter if smoke is observed.
- Service of mLabs® ImmunoMeter should be performed only by Micropoint Bioscience’s service engineers.
- Warranty will be voided if mLabs® ImmunoMeter is opened or disassembled by user.

1.5 Symbols and Explanations

Symbol	Description	Symbol	Description
	Lot Number		Expiration Date
	Caution. Read Carefully.		Fragile
	Grounded		This Side Up
	Name and Address of Manufacturer		Avoid Liquid Spills
	Manufacture Date		European Authorized Representative
	Hot Surface		Stacked no more than 5 layers
	For In Vitro Diagnostic Use Only	**SN**	Serial Number
PN	Part Number	**Rev.**	Revision

2. Installation and Configuration

2.1 Instrument Set Up

- Place the mLabs® ImmunoMeter and accessories on a flat workbench.
- Do not leave mLabs® ImmunoMeter to exposed to direct sunlight or place it near an area with a high heat source or strong magnetic field.
- Please contact your local Micropoint distributor if there is any damage caused during shipping process.

2.1.1 Connect the power adapter to mLabs® ImmunoMeter

- Connect the power adapter and the power cable.
- Plug the power adapter into mLabs® ImmunoMeter (see Fig. 1-7(8)).
- Plug the other end of the power cable into power outlet.

2.1.2 Install the Printing Paper

- Pull and open the cover of thermal printer (see Fig. 1-7(13)) and insert printing paper according to Fig. 2-1.
- Allow a small portion of the printing paper to be extended outside the printing paper compartment. Close the cover and the printing paper will be fed automatically.

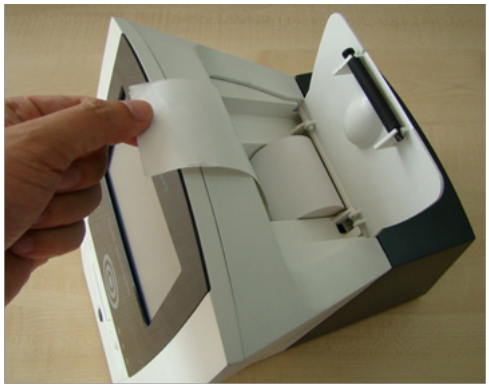


Fig. 2-1

CAUTION: The thermal printing compartment may be hot during operation!
It is recommended to handle the thermal printer after it has cooled down.

2.1.3 Install the Barcode Scanner

- Connect the barcode scanner into the RS232 Serial Port of the mLabs® ImmunoMeter (see Fig 1-7(9)).
- Follow the instructions supplied with the barcode scanner.

2.2 Power Up and Configure mLabs® ImmunoMeter

2.2.1 Power up the mLabs® ImmunoMeter

- Press and hold the black “Power On/Off” button on the front of the instrument until the green power light turns on.
- A “System Check” status shows on the screen with the status light on before “Main Menu” displays.
- Wait for up to 1 minute to allow “Main Menu” screen to appear as shown in Fig. 2-2.

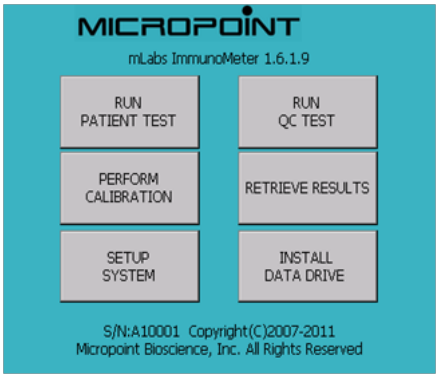


Fig. 2-2

(Each mLabs® ImmunoMeter may have different software version and S/N number than shown.)

2.2.2 Configure the mLabs® ImmunoMeter

- Touch "SETUP SYSTEM" on the screen as shown in Fig. 2-2. The setup menu will display as in Fig. 2-3.

Fig. 2-3

- Adjust the following settings:
  1. Time and Date
  2. Printing Mode
  3. Instrument's Calibration Frequency
  4. User ID
- After setting up the basic parameters for mLabs® ImmunoMeter, touch "SAVE" to save the configuration or touch "BACK" to return to previous menu.

2.2.2.1 Set Time and Date

- Use the pull-down menu and/or up-and-down arrows as shown in Fig. 2-3 to set the correct date and time.

2.2.2.2 Set Printing Mode

- Choose printing mode by touching the open circle to either "AUTOMATIC" or "MANUAL" as shown in Fig. 2-3.

2.2.2.3 Set the Calibration Frequency

- As shown in Fig. 2-3, select "NONE" or "30 DAYS" on "CALI. FREQ" to select the instrument calibration interval.

2.2.2.4 Set User ID

- Each instrument has a default user ID and password as “000001” and “123”, respectively. Touch “ADMIN” as shown in Fig. 2-3 and enter this user ID and password as shown in Fig. 2-4. In the screen as shown in Fig. 2-5, only the administrator can add or delete a user ID, and edit user information such as status, authorized date (start-end), password, and ID BYPASS mode. Authorized users can modify their passwords only.
- There is an option for the ID BYPASS ON as shown in Fig. 2-5. If this option is selected (designated by the mark, ☑), no USER ID is required when performing “Run Patient Test” or “Run QC Test”; the mLabs® ImmunoMeter will recognize the user as default 000001. If this option is not selected and left blank as ☐, the operator is required to enter a USER ID each time before running test (“Run Patient Test” or “Run the QC test”).

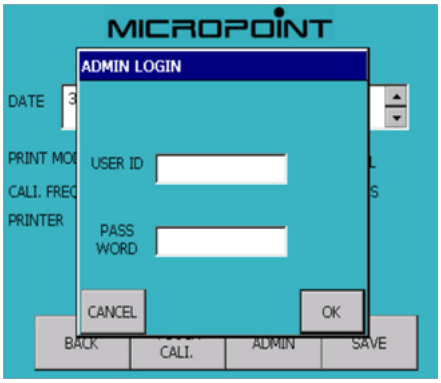


Fig. 2-4

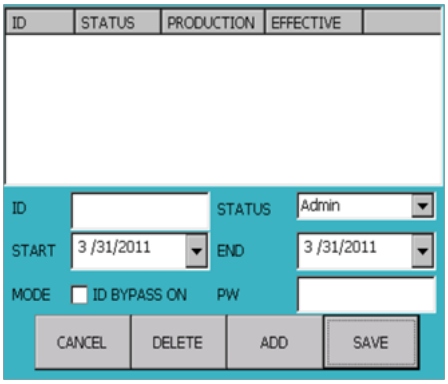


Fig. 2-5

2.3 Calibrate mLabs® ImmunoMeter using Calibration Cartridge

- The mLabs® ImmunoMeter will prompt user to perform calibration test when the calibration interval in “Cali. REQ” is set “30 DAYS” and when the calibration is due.
- To perform a calibration, touch “PERFORM CALIBRATION” in main menu, a screen as shown in Fig. 2-6 will display.

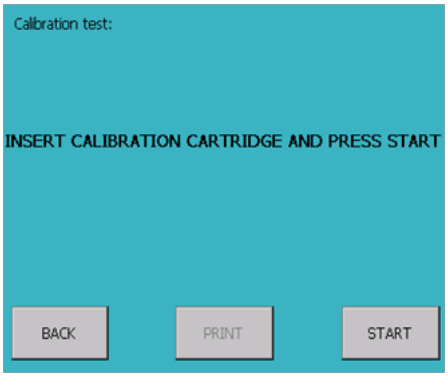


Fig. 2-6

- Press cartridge holder eject button (see Fig 1-7(6)) to eject the cartridge holder.
- Place the provided Calibration Cartridge with barcode side facing up in the cartridge holder and touch “START”.
- mLabs® ImmunoMeter will perform calibration automatically. After calibration is completed, mLabs® ImmunoMeter will display either “CALIBRATION PASS” or “CALIBRATION FAIL” on the screen.
- After calibration is complete, the calibration cartridge will be ejected. Remove the calibration cartridge from the holder and replace it back to the original zip-locked pouch. DO NOT DISPOSE OF THE CALBRATION CARTIDGE.
- Press cartridge holder eject button to bring the cartridge holder back into mLabs® ImmunoMeter.
- Do not add sample or control or any liquid into the Calibration Cartridge!
- If calibration fails, contact the local Micropoint distributor for further advice.

3. Operation

3.1 Install the Data Drive

- Prior to running any assay, the Data Drive for that Assay Lot must be installed into the mLabs® ImmunoMeter. The Data Drive provides Lot-specific information and the expiration date, and is only required to be installed once for each Lot. The mLabs® ImmunoMeter can store information from different Lots. If the maximum is exceeded, the oldest entry is overwritten. A Lot-specific Data Drive is provided with each test kit.
- Insert the Data Drive (USB drive) into a USB port at the rear of mLabs® ImmunoMeter.
- From the main menu, select “INSTALL DATA DRIVE”
- A screen as shown in Fig. 3-1 will display.
- Touch “Install” as shown in the bottom right corner of Fig. 3-1. The Data Drive will be installed automatically.

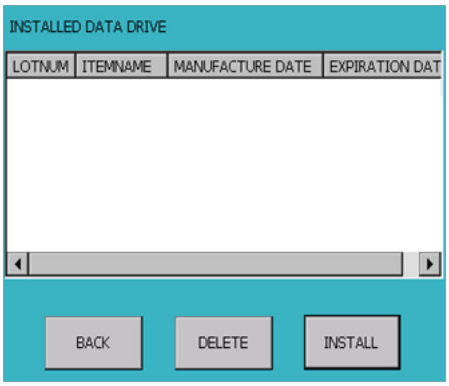


Fig. 3-1

- The screen displays “PLEASE WAIT, INSTALLATION IN PROGRESS” while installing the Data Drive. After the Data Drive is successfully installed, the screen will display “DATA DRIVE FOR TEST CARTRIDGE INSTALLED!” Touch the upper right corner “OK” to confirm. As shown in Fig. 3-2.

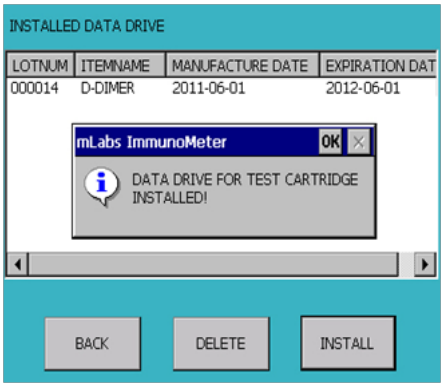


Fig. 3-2

- Remove the Data Drive (USB drive) from mLabs® ImmunoMeter after installing the Data Drive.
- Lot number information on the Data Drive will be displayed on screen after the Data Drive is successfully installed. Fig. 3-3 shows a typical display after the Data Drive is successfully installed for D-Dimer Cartridge with lot number 000014. “Lot Num” represents the Lot Number of the cartridges and “ITEMNAME” is the type of test cartridge. The lot manufacture date and expiration date are also shown on the screen.

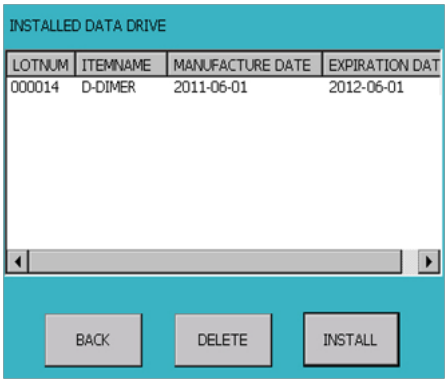


Fig. 3-3

- To delete data drive, select the data drive you want to delete, then touch “DELETE” and input the admin user name and password. It is not recommended to Delete any Data Drive from the mLabs® ImmunoMeter if not necessary.
- Touch “BACK” to return to the Main Menu.

3.2 Run QC test

Install the Data Drive for QC test before the QC test is conducted. Follow the steps described in 3.1

3.2.1 Prepare QC Sample and test Cartridge

- Follow the instructions provided with QC materials to prepare liquid QC Samples.
- QC lot number and expired data will be on the QC material label.
- Add liquid QC samples into cartridge according to QC material instructions. Follow the instructions in 3.2.2, “Running QC Test” after QC liquid sample is added into cartridge.

3.2.2 Run QC Test

- Touch “RUN QC TEST” on the Main Menu screen.
- Enter USER ID as shown in Fig. 3-4 and touch “OK”.
- Enter the QC lot number as shown in Fig. 3-5 and touch “OK”.

Fig. 3-4

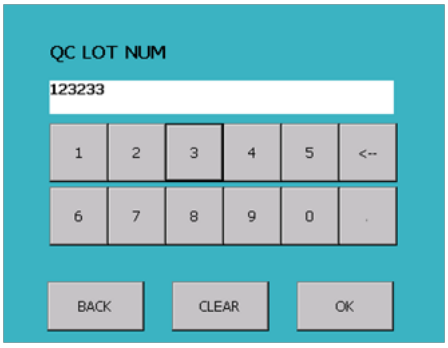


Fig. 3-5

NOTE: If an unregistered or wrong user ID is entered, the system will prompt as shown in Fig. 3-6(1). If the Data Drive for the QC lot is not installed, system will prompt as shown in Fig. 3-6(2). If the Data Drive for the test cartridge is not installed, system will prompt as shown in Fig. 3-6(3).

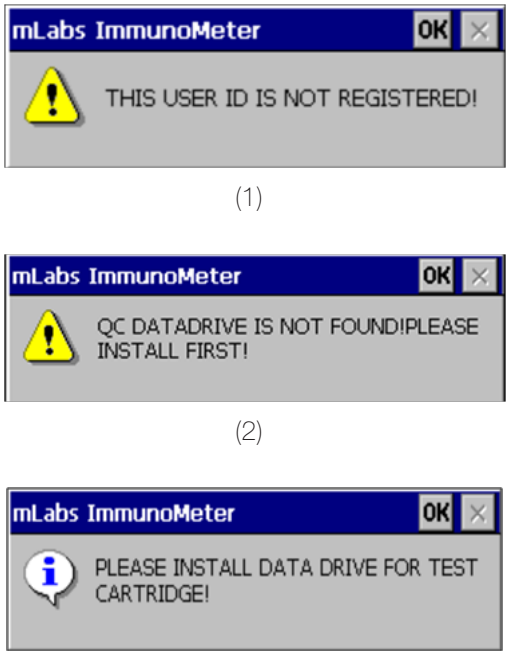


Fig. 3-6

- Insert the QC test sample Cartridge and touch “START”.
- mLabs® ImmunoMeter will perform QC test automatically, and display results as shown in Fig. 3-7.

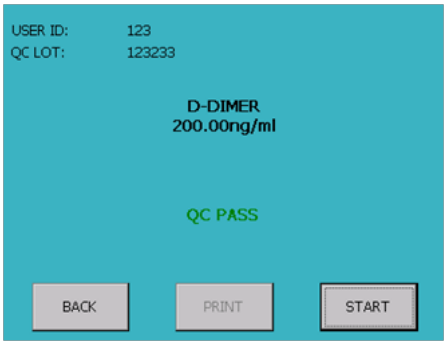


Fig. 3-7

(Result shown for reference only)

3.3 Test Patient Sample

- Prepare cartridge according to the package insert of the test kit.
- From main menu, touch “RUN PATIENT TEST”.

3.3.1 Enter User ID

- Enter the user ID as shown in Fig. 3-8.
- Touch “OK”. A screen as shown in Fig. 3-10 will display.

NOTE: If you enter an unregistered user ID, system will prompt as Fig. 3-9.

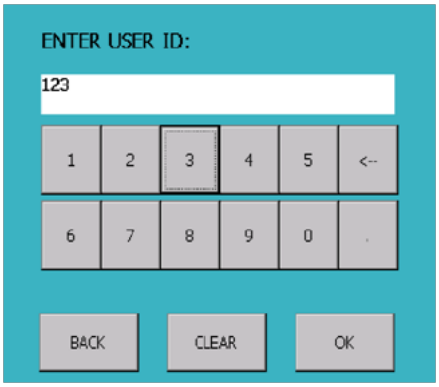


Fig. 3-8

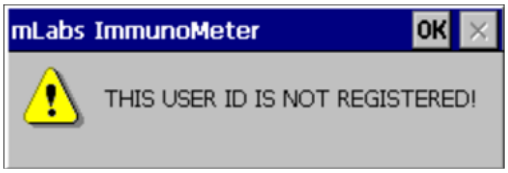


Fig. 3-9

3.3.2 Enter Patient ID

- Enter an up to 15 digit number as patient ID. Fig. 3-10 shows an entry for Patient ID “789”. Touch “OK” to advance to next step.

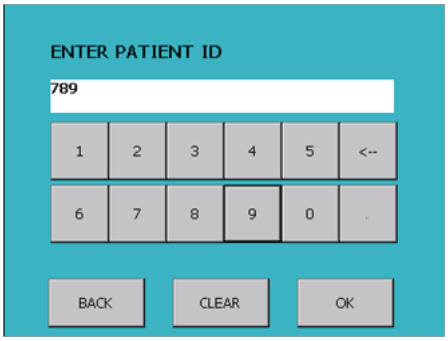


Fig. 3-10

3.3.3 Start the Test

- Press cartridge holder eject button (see Fig. 1-7(6)). The cartridge holder will be ejected.
- mLabs® ImmunoMeter will display test menu as Fig. 3-11.

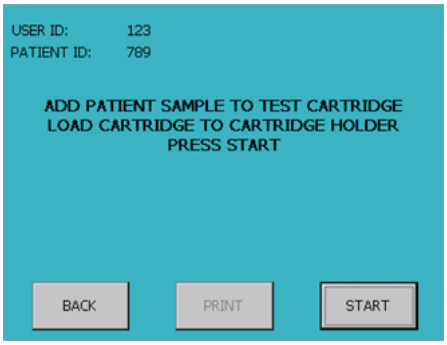


Fig. 3-11

- Add sample into the cartridge follows instructions in the Package Insert.
- Put the cartridge into the cartridge holder and touch “START” as shown in Fig. 3-11 to start the test.
- When the test is complete, the cartridge holder will be ejected automatically. The test results will be displayed on the screen and saved automatically (Fig. 3-12).

Fig. 3-12

(Result shown for demonstration purposes only)

- Results will automatically be printed if mLabs® ImmunoMeter is configured for “AUTOMATIC” printing, see 2.2.2 Configure the mLabs® ImmunoMeter. If printer’s mode is set at “MANUAL”, touch “PRINT” to print the result.
- Touch “Back” to return to previous menu to enter a new Patient ID for next patient sample.

3.4 Retrieve Results

- Touch “RETRIEVE RESULTS” on the main menu. The screen will display the SEARCH OPTIONS as shown in Fig. 3-13:

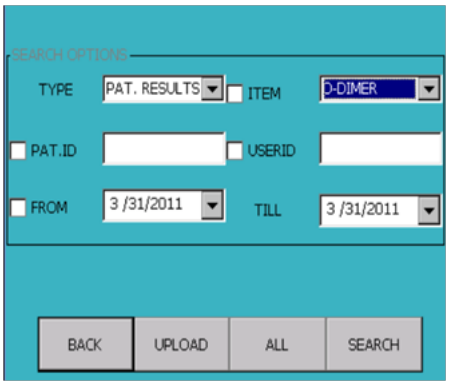


Fig. 3-13

- In the “SEARCH OPTION” menu as shown in Fig. 3-13, users can select one or more options: (1) Result TYPE, (2) Test ITEM (analyze), (3) Patient ID, (4) User ID or (5) Test date (FROM-TILL). Results will be displayed according to search selections.
- Touch “ALL” to see all test results as shown in Fig. 3-14.
- Touch “PRINT SEL” to print the selected results. Select “PRINT ALL” to print all the displayed results.
- Touch “DELETE” to delete any checked data.
- Touch “BACK” to return to the previous menu.

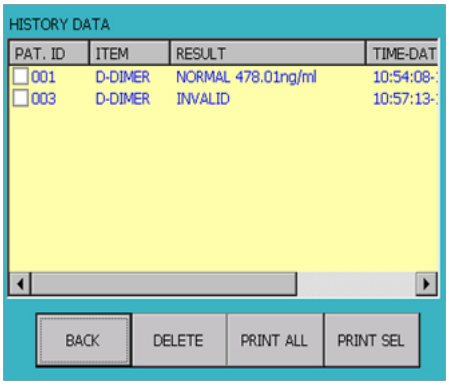


Fig. 3-14

3.5 Export Data to an External USB Drive

- Touch “RETRIEVE RESULTS” on main menu. The screen will display the SEARCH OPTIONS as shown in Fig. 3-13.
- Insert an external USB drive to the rear of mLabs® ImmunoMeter (see Fig. 1-7(12)). For your data safety, it’s strongly recommended to use the USB drive authorized by Micropoint Bioscience, Inc.
- Touch “UPLOAD” as shown in Fig. 3-13. mLabs® ImmunoMeter will prompt to input the USER ID and password, only the admin user with a correct ID and password can access this function as shown in Fig. 3-15.

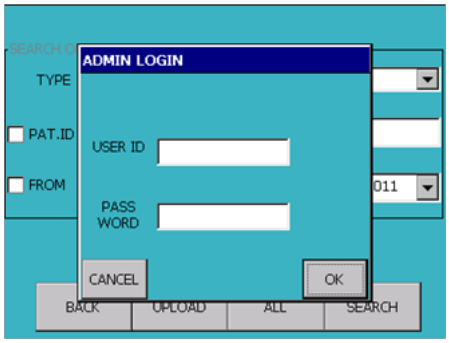


Fig. 3-15

- The mLabs® ImmunoMeter creates a folder named “Data” in the USB drive and upload all original data and test results to the newly created “Data” folder. The uploading process is shown in Fig. 3-16, with the “progress bar” indicating the status of uploading process.
- The “progress bar” will disappear after finishing uploading. Do not remove the USB drive until the uploading process is completed. If the USB drive removed during the uploading process, the data will be permanently lost.
- As shown in Fig. 3-16, system prompt whether to keep the patient results during this upload process, select “Yes” to keep the patient results in mLabs® ImmunoMeter, and “No” to remove all the patient result from mLabs® ImmunoMeter. Also, system prompt whether to keep the QC and calibration result, select “Yes” to keep the result, and “No” to remove all the result from mLabs® ImmunoMeter as shown in Fig. 3-17 and 3-18.
- When upload is completed the screen will indicate data transfer completed as shown in Fig 3-19. Touch “OK” to close the window before remove the USB drive. Touch “BACK” to return to the main menu.

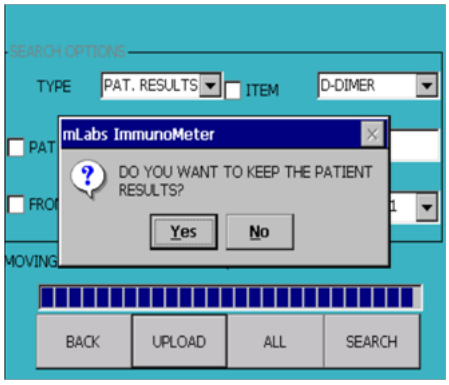


Fig. 3-16

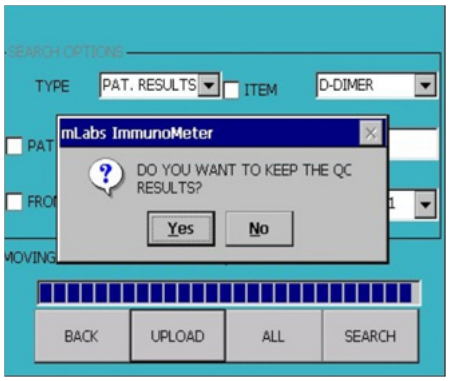


Fig. 3-17

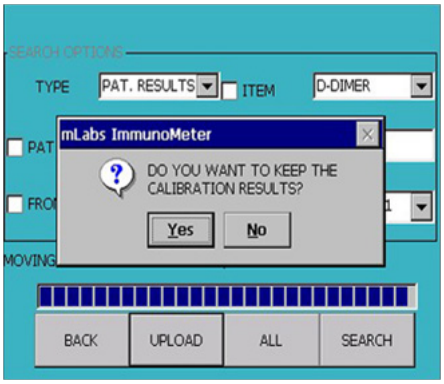


Fig. 3-18

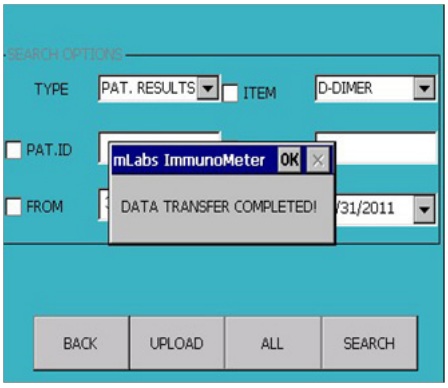


Fig. 3-19

CAUTION:

(1) After the data is saved onto an external USB drive, the data stored in mLabs® ImmunoMeter will be permanently removed if you select “No” as shown in Fig 3-16.

(2) Please ensure that there is no ”Data” file in the external USB drive before performing the data uploading process from mLabs® ImmunoMeter.

4. Maintenance

4.1 Clean mLabs® ImmunoMeter

- Unplug mLabs® ImmunoMeter prior to cleaning.
- Clean the exterior surface and the cartridge holder of mLabs® ImmunoMeter with a lint-free wipe.
- Do not immerse mLabs® ImmunoMeter in cleaning liquid.
- Avoid spilling liquids on the mLabs® ImmunoMeter and related accessory devices.

4.2 Calibrate Touch Screen

- From the main menu touch “System Setup”, then “Touch Cali”. The prompt on the screen shows whether continue the calibration shown as Fig. 4-1.

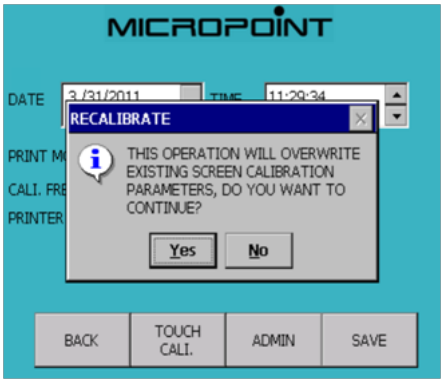


Fig. 4-1

- Touch “Yes” to start calibration, and a cross cursor will be displayed on the screen.
- Touch the middle of the cursor with a blunt tip (recommend to use touch pen) until the cursor move to the next position, and repeat the operation until the cursor disappears from the screen. The cursor moves as the broken line shown in Fig. 4-2.

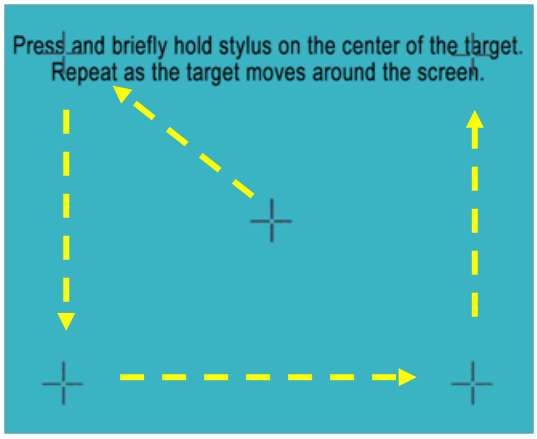


Fig. 4-2

- Touch any position of the screen according to the prompt, and the system will save the calibration parameter automatically and return. As shown in Fig. 4-3.

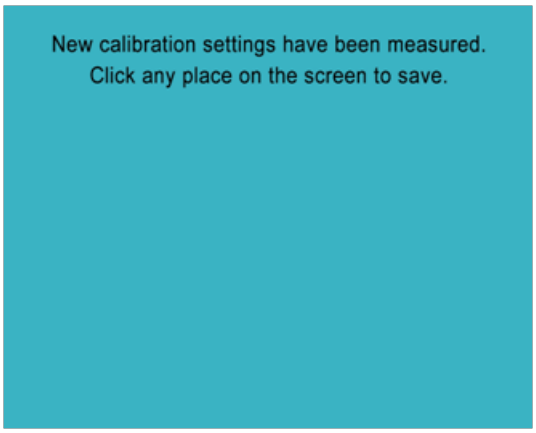


Fig. 4-3

5. Troubleshooting

Commonly encountered problems are listed below, along with its probable causes and recommended corrective actions:

Problems	Probable Causes	Corrective Actions
Cannot Power On	Power cord is not plugged in	Ensure power cord is connected to power outlet socket
	ImmunoMeter failure	Reboot mLabs® ImmunoMeter
Power Light does not illuminate	ImmunoMeter is not plugged in	Ensure power cord is connected to power outlet socket
	ImmunoMeter failure	Reboot mLabs® ImmunoMeter
Status Light is always on	Testing or initializing	Wait for completion of the process
	ImmunoMeter failure	Reboot mLabs® ImmunoMeter
LCD Screen does not appear	Power cord is not plugged in	Ensure power cord is connected to socket
	It takes ~1 min for screen to appear after power on	Please wait for 1-2 min
	ImmunoMeter failure	Reboot mLabs® ImmunoMeter
LCD Screen cannot be operated or inaccurate touch location	LCD Screen does not respond after powering on	Please wait for 1-2 min or reboot mLabs® ImmunoMeter
	Screen is not calibrated	Calibrate screen (refer to 4.3)
Eject Button does not work	Inadequate pressure	Press button again with stronger force
	ImmunoMeter failure	Reboot mLabs® ImmunoMeter
Cartridge holder cannot be ejected	Objects are obstructing its movement	Clean the obstructing objects
	ImmunoMeter failure	Reboot mLabs® ImmunoMeter
Cartridge holder cannot be closed	ImmunoMeter is not sitting on a flat surface	Set mLabs® ImmunoMeter on a flat surface
	Objects are obstructing its movement	Clean the obstructing objects
Excessive noises during movement of cartridge holder	Changes such in surrounding temperature or humidity	No action is needed.
	Test cartridge is not inserted correctly	Reinsert the test cartridge

Problems	Probable Causes	Corrective Actions
Data Drive is not being recognized	Not enough time for mLabs ImmunoMeter to recognize the Data Drive	Wait for about 10 Sec. and repeat operation
	Slow or no response	Reinsert Data Drive and repeat operation
	Data Drive is already installed	Proceed with test
	USB port is loose	Reinsert Data Drive and repeat operation
	Incorrect Data Drive	Please contact with local dealer to exchange the Data Drive
Test cartridge cannot be inserted onto cartridge holder	Objects are obstructing its insertion	Remove existing objects
	Cartridge is not inserted properly	Adjust and reinsert cartridge
Unable to perform test	DATA DRIVE is not install	Install Data Drive (refer to 3.1)
	Input unregistered or wrong user ID User ID or no patient ID or patient ID is more than 15 digits	Input correct User ID and correct Patient ID
	Test cartridge is not inserted	Insert test cartridge
Unable to initialize data query	Data is already exported	Locate the already exported data
	System Failure	Reboot mLabs® ImmunoMeter
Unable to upload data with external USB device	USB port is loose	Reinsert external USB drive and repeat operation
	External USB drive has existing data in it	Remove existing data in the external USB drive
Unable to print test results	Print or automatic print is not selected	Refer to 3.3 and 3.4
	Nothing is selected for printing	
	Run out of thermal printing paper or not properly installed	Reinstall thermal printing paper
Measurement failure	Sample size incorrect-too little sample	Retest sample with a new test cartridge using adequate test samples
	Improper anticoagulated samples or body fluids	Retest sample with a new test cartridge using proper test samples
	Sample running slowly	Possibly due to cold test cartridges or sample, high hematocrit with sample.

If additional assistance is needed, please contact Micropoint Bioscience Technical Support.

Micropoint Bioscience Technical Support

TEL: +1-408-588-1682

EMAIL: techsupport@micropointbio.com

IMPORTANT NOTES: Service shall be conducted only by Micropoint Bioscience's service engineers. Warranty will be voided if mLabs® ImmunoMeter is disassembled by the user.

**Micropoint Bioscience Inc's (MBI) express and implied warranties (including implied warranties of merchantability and fitness) are conditioned upon observance of MBI's published directions with respect to the use of MBI's products.

6. Warranty

Limited Warranty

1. Use of the mLabs® ImmunoMeter. The mLabs® ImmunoMeter (the "Meter"), manufactured by Micropoint Bioscience, Inc. ("Micropoint"), is designed only for measurement of test results obtained using mLabs® cartridges manufactured by Micropoint. Proper adherence to the instructions in the user manual and package inserts is critical to proper operation.

WARNING: Failure to comply with the user manual could lead to inaccurate results and resultant incorrect diagnosis which could result in injury or death.

2. Defects Covered. Subject to the terms and conditions of this Limited Warranty, Micropoint warrants to the original purchaser of the Meter ("Purchaser") that the Meter will be free from material defects in material and workmanship, under normal use and service, for one year from the date of purchase.

3. Remedy. In the event the Meter does not conform to the above warranty, then as Micropoint's sole responsibility and Purchaser's sole remedy, Micropoint will repair or replace the Meter, at Micropoint's option, free of charge. This warranty will apply only if Purchaser notifies Micropoint of the defect in writing during the warranty period, and ships the Meter back to Micropoint at the expense of Purchaser, along with documentation sufficient to establish the date of purchase. Before returning a defective Meter, Purchaser must obtain a Return Material Authorization ("RMA") number and return instructions from Micropoint Technical Support by calling +1 408 588 1682.

4. Exclusions. The only user serviceable parts of the Meter are printing paper and the printing paper door. Tampering with any other portion of the Meter, abusing the Meter or using the Meter in a manner inconsistent with its user manual will void this warranty. This warranty does not apply to Meters that have been damaged during shipment, by improper storage or through accident, Meters that have been altered or modified, or Meters that have been subject to abuse. This warranty does not guarantee the uninterrupted operation of the Meter.

5. Warranty on Repairs and Replacements. Replacement Meters, and repairs which Micropoint makes pursuant to the above warranty, shall carry the greater of a thirty-day warranty period or the balance of the original warranty period.

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The mLabs® ImmunoMeter is CE marked and SFDA approved. It is distributed outside of the US.
For more information or to order the mLabs® ImmunoMeter, please email: info@micropointbio.com.
P/N 99010015401 Rev. A1